IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION This document relates to: *All Actions*	No. 1:19-md-2875-RBK-KMW

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO APPEAL OF SPECIAL MASTER ORDER NO. 84

INTRODUCTION

More than a year after the close of fact discovery, the ZHP Defendants served third-party Valisure with a subpoena seeking information related to its 2019 Citizen Petition, which was known to the ZHP Defendants when it was filed. [ECF 863; 2227-4, 2217-4.] Specifically, the ZHP Defendants belatedly requested information to determine whether the drugs tested by Valisure included brand name valsartan drugs Diovan or Exforge. [ECF 2217-4, 2476 at 4.] The ZHP Defendants' subpoena was untimely, sought abjectly unreliable information, and was properly quashed by Special Master Vanaskie.

Contrary to the ZHP Defendants' assertions, CMO 23 *does* control. Fact discovery had closed over a year before the ZHP Defendants served their subpoena and the ZHP Defendants do not even try to claim that they were not aware of the information forming the basis of the subpoena until after it had closed. The "ZHP Defendants were aware of the Valisure Citizen Petition for many months before seeking identification of the NDC numbers for the substances disclosed in the Petition." [ECF 2476 at 4.] Defendants nonetheless failed to act, waiting until well after the close of discovery, exchange of expert reports, and subsequent briefing to request information wholly irrelevant to the litigation. Indeed, after hundreds of hours of testimony, no party ever sought testimony about Valisure and the ZHP Defendants never bothered to conduct their own testing to determine whether Exforge or Diovan contained nitrosamines. [*See id.*]

Plaintiffs accordingly request that the Court DENY the appeal of Special Master Order 84.

FACTUAL BACKGROUND

On February 11, 2021, this Court issued CMO 23, providing that the deadline for the first phase of fact discovery was June 1, 2021 and the deadline for the second phase of fact discovery was October 4, 2021. [ECF 863.] Subsequently, on December 14, 2022, Defendant ZHP gave

notice that it was serving third-party laboratory Valisure with a subpoena. [ECF 2217-4.] Valisure objected to the subpoena on December 28, 2022 and indicated it would not produce documents. [ECF 2217-6.]

By this point, it had been more than two years since Plaintiffs were ordered by the Court to serve any and all subpoenas they intended to serve upon all third parties by October 15, 2020 [ECF 575.] Plaintiffs' subpoenas were subject to extensive briefing by the Parties. [*See* ECF 652 *et seq.*] During that protracted briefing, the Parties met and conferred countless times and the Court heard hours of oral argument regarding third-party discovery. For their part, the ZHP Defendants have taken testimony from approximately sixty physicians and third-party payors initiated in advance of the discovery deadline. The ZHP Defendants have not pursued any other third-party discovery after the discovery deadline except for the Valisure subpoena.

The ZHP Defendants filed a Motion to Compel Compliance with the Valisure Subpoena. Plaintiffs opposed the Motion and filed a Cross-Motion for a Protective Order and to Quash the Valisure Subpoena.[1] On August 29, 2023, Special Master Vanaskie entered Special Master Order 84, denying the ZHP Defendants' Motion to Compel, granting Plaintiffs' Motion, and quashing the Valisure Subpoena. This appeal followed.

LEGAL ARGUMENT

I. STANDARD OF REVIEW

1. Objection to Special Master's Order

The Court reviews a party's objections to a Special Master's findings of fact and legal conclusions *de novo*. Fed. R. Civ. P. 53(f)(3)–(4). "This, however, does not require the reviewing

[1] The ZHP Defendants do not, in this appeal, challenge Plaintiffs' standing to seek a protective order quashing the subpoena. Plaintiffs nonetheless have standing to do so. *See, e.g., Aetrex Worldwide, Inc. v. Burten Dist. Inc.*, 2014 WL 7073466, at *4 (D.N.J. Dec. 15, 2014).

court to hear new arguments. In fact, courts generally 'exclude evidence of new arguments on objections because systematic efficiencies would be frustrated and the Special Master's role reduced to a mere dress rehearsal." *Net2Phone, Inc. v. Ebay, Inc.*, 2008 WL 8183817, at *4 (D.N.J. June 26, 2008) (quoting *Dunkin' Dounts Franchised Restaurants LLC v. Mehta*, 2007 WL 2688710, at *1–2 (W.D. Pa. Sept. 11, 2007)).

2. Subpoenas

"A Rule 45 subpoena must fall within the scope of proper discovery under Fed. R. Civ. P. 26(b)(1)." *Schmulovich v. 1161 Rt. 9 LLC*, 2007 WL 2362598, at *2 (D.N.J. Aug.15, 2007). Although the "scope of discovery is broadly construed, it is not without its limits and may be circumscribed." *In re Novo Nordisk Sec. Litig.*, 530 F.Supp.3d 495, 501 (D.N.J. 2021). Courts have the authority to quash or modify subpoenas which fall outside the scope of permissible discovery" as defined by Rule 26(b). *Korotki v. Cooper Levenson, April, Niedelman, & Wagenheim, P.A.*, 2022 WL 219519, at *2 (D.N.J. June 17, 2022). "Applying Rules 26 and 45, the Court must balance several competing factors in assessing the reasonableness of the subpoenas: (1) relevance, (2) the party's need for the documents, (3) the breadth of the document request, (4) the time period covered by it, (5) the particularity with which the documents are described, (6) the burden imposed, and (7) the subpoena recipient's status as a nonparty to the litigation." *Id.* at *3. The relevancy standard "is not so liberal as to allow a party to roam in shadow zones of relevancy and to explore matter which does not appear germane merely on the theory that it might become so." *See*, *e.g.*, *Costantino v. City of Atlantic City*, 2015 WL 12806490, at *2 (D.N.J. Nov. 4, 2015).

Courts have authority to issue protective orders and quash subpoenas pursuant to the Rules of Civil Procedure, but also as a matter of inherent authority. First, Courts have inherent discretion to enforce their own scheduling and case management orders. *See Lockhart v. Willingboro High*

Sch., 2017 WL 1145996, at *4 (D.N.J. May 3, 2017). If a subpoena is deemed untimely, the Court has the authority to quash the subpoena even without motion.[2] Second, Courts are entitled to issue a protective order if the requesting party demonstrates either that the requested discovery does not fall within Rule 26, or that the requested discovery imposes an unreasonable burden, or is otherwise interposed for purposes of harassment or undue delay. Fed. R. Civ P. 26(b)(2)(C)(iii).

II. THE ZHP DEFENDANTS' SUBPOENA TO VALISURE WAS UNTIMELY

It is indisputable that the ZHP Defendants' subpoena to Valisure was served over a year after the fact discovery deadlines established by CMO 23. [ECF 863] The ZHP Defendants do not deny this but claim that, despite the deadlines expressly set out in CMO 23, the subpoena to Valisure was not untimely because the Order was "never intended to preclude additional fact discovery." [ECF 2494-1 at 5.] Fact discovery in this litigation cannot proceed indefinitely and without restraint, as the ZHP Defendants allege. Rather, the deadlines clearly established in CMO 23 govern and fact discovery is over. The ZHP Defendants had ample time to issue a subpoena during fact discovery and cannot credibly claim that there was a reasonable basis for delay. [ECF 2476 at 4–5.] The failure to issue the subpoena within the CMO 23 deadlines render it untimely.

1. The Deadlines in CMO 23 Are Controlling

The ZHP Defendants, relying on a single word in CMO 23, first argue that the Court intended for fact discovery to continue beyond the deadlines listed in the Order. [ECF 2494-1 at 4 ("The reference to the 'first' phase of discovery expressly confirms that further discovery is

[2] This authority is also rooted in Fed. R. Civ. P. 16(f) which authorizes a district court to issue, *sua sponte*, "any just orders … if a party or its attorney … fails to obey a scheduling or other pretrial order." *Mulero-Abreu v. P.R. Police Dep't*, 675 F.3d 88, 91 (1st Cir. 2012) (citing Fed. R. Civ. P. 16(f)(1)(C)). Thus, the Court had authority to quash the subpoena at issue even in the absence of a Motion by Plaintiffs.

contemplated.").] This reliance is misplaced. Discovery in this case was to be conducted in two phases, the first phase ending June 1, 2021 and the second (final) phase, ending October 4, 2021. [ECF 863.] Third-party discovery was to be completed by the end of the second phase of discovery on October 4, 2021. [*Id.*] The ZHP Defendants have not identified any order of this Court setting alternative dates for third-party discovery. [*See generally* ECF 2494-1.]

Valisure's Citizen Petition concerning nitrosamine impurities in valsartan-containing drugs was filed on June 13, 2019. [ECF 2227-4.] Yet, the ZHP Defendants did not serve a third-party subpoena on Valisure during either of the two phases of fact discovery. Instead, they sat on their hands, either due to lack of diligence or for strategic purposes, and waited over a year until the second (and final) phase of fact discovery had closed to serve their third-party subpoena on Valisure. [ECF 2217-4]. **The complete lack of any justification for the delay in seeking this information is as dispositive as the delay itself**.

The ZHP Defendants assert that the "reference to the 'first' phase of discovery expressly confirms that further discovery is contemplated." [ECF 2494-1 at 4.] While the Court did contemplate a second phase of discovery as demonstrated by CMO 23, the second phase of discovery concluded in October 2021—over a year before issuance of the Valisure subpoena. [ECF 863.] After fact discovery closed, the Court revised the scheduling order. [ECF 1679.] That scheduling order did not provide for additional fact discovery; to the contrary, it established deadlines for the expert reports and briefing that would be based on the fact discovery already conducted. [*Id.*] No fact discovery was contemplated beyond the second phase of discovery. [ECF 863, 1679.] Certainly, additional "phases" of fact discovery are not intended to be added by fiat of a party, let alone after the exchange of expert reports and extensive briefing focused in large part on the bases for the opinions at issue.

The ZHP Defendants next argue that their subpoena was timely because the Court permitted subsequent discovery in other—unrelated—parts of the litigation. [ECF 2494-1 at 5.] As an initial matter, the ZHP Defendants' failure to raise this argument before the Special Master precludes consideration of this argument now. *Net2Phone, Inc. v. Ebay, Inc.*, 2008 WL 8183817, at *4 (D.N.J. June 26, 2008) ("[I]n an appeal of a Special Master's decision, the parties cannot raise entirely new arguments for the first time." (quotations omitted)). This argument also fails on the merits. The ZHP Defendants willfully ignore the distinction between the third-party fact discovery *they* seek and the subsequent discovery permitted by the Court. The Court has permitted additional discovery in limited, unique circumstances as follows:

- Case-specific discovery to prepare for the TPP trial as contemplated by the Parties[3]
- Losartan/irbesartan discovery in a separate part of the litigation proceeding on an entirely different timeline
- Wholesaler/retailer discovery requested *prior to* the discovery deadlines with production deferred until after the deadline

The ZHP Defendants allude to Fed. R. Civ. P. 16(b)(4), which permits courts to modify schedules for "good cause" but fail to identify any evidence that the Court took action to modify the schedule for third-party discovery in this case. [ECF 2494-1 at 4.]. Nor is there any good cause shown – to the contrary, the record shows inexcusable delay.

2. Defendants Lacked Good Cause to Delay

Defendants cannot credibly claim that they had "good cause" for delay because they were aware when the Citizen Petition that forms the basis of this subpoena was published to the public domain on June 13, 2019. [ECF 2227-4.] Defendants consequently had more than two years to

[3] The ZHP Defendants make much out of the Court's language that the "… timeliness objection does not factor into the decision." [ECF 2249.] They ignore, the context of this statement, namely, that "Because MSPRC does not seek denial of the TPP Defendants' request on timeliness grounds and the fact that case-specific fact discovery was contemplated after the TPP Plaintiff was identified, MSPRC's timeliness objection does not factor into the decision…" [*Id.*]

subpoena records from Valisure, to the extent they believed such records were somehow relevant to their claims and defenses. Instead, Defendants opted to subpoena this entity after Plaintiffs submitted their expert liability reports and Daubert briefing was filed, after Plaintiffs submitted their motion for Class Certification, and after the close of fact discovery. Defendants' own document productions (completed prior to the close of fact discovery), likewise undercut the hyperbolic sense of urgency in their motion: the fact remains that Defendants were aware of the existence of the Valisure Citizen's petition in June of 2019. [*See, e.g.*, ECF 2227-3, 2227-4, 2227-5, 2227-6, 2227-7.]

Discovery deadlines are not arbitrary. Special Master Vanaskie explained that discovery deadlines, in general, are "important" because they "enable the record to be set for such significant events as class certification and summary judgment motions." [ECF 2476 at 4.] In this case specifically, The ZHP Defendants sought to pursue third-party discovery "after Plaintiffs presented their expert witness reports on liability, and well after briefing and decisions on class certification decisions" despite being aware of the Valisure Citizen Petition for "many months" before. [*Id.*][4] The scheduling orders in this case demonstrate that there were two phases of fact discovery, followed by expert reports and briefing which were reliant on the productions made during fact discovery. [ECF 863, 1679.] To permit subsequent third-party discovery well after discovery, expert, and briefing deadlines had passed would prejudice Plaintiffs and further protract this

[4] Special Master Vanaskie concluded that the subpoena was untimely because it was issued after "Plaintiffs had presented their expert witness reports on liability and well after briefing and decisions on class certification issues." [ECF 2476 at 4.] Defendants' argument that this conclusion is erroneous and should be vacated because "Rule 23 motions were still pending and although expert reports concerning liability issues had been disclosed by Plaintiffs" they were focused on manufacturer-specific issues, ignores the logic of the Special Master's findings. [ECF 2494-1 at 6.]

litigation.[5] Special Master Order 84, quashing the subpoena as untimely, is consistent with the standard practice of courts in this jurisdiction, which routinely quash subpoenas served not only *after* the close of discovery but also days or weeks *before* the close of discovery as untimely where defendants had adequate time to seek earlier discovery. *Duardo v. City of Hackensack*, 2021 WL 35089781, at *3 (D.N.J. Aug. 9, 2021). Here, the Valisure Subpoena was untimely and was properly quashed because Defendants had "ample time" to seek third-party discovery on the Valisure Citizen Petition but waited until discovery had been closed for over a year to serve their subpoena on Valisure. *Id.*; [ECF 2476 at 4.]

III. THE ZHP DEFENDANTS' SUBPOENA TO VALISURE SEEKS IRRELEVANT INFORMATION

At a minimum, to be discoverable, information must be relevant. Fed. R. Civ. P. 26(b)(1). "A nonparty is 'afforded greater protection in discovery and nonparty subpoenas must meet a higher standard of relevance than subpoenas directed toward parties.'" *Duardo v. City of Hackensack*, 2021 WL 34089781, at *3 (D.N.J. Aug. 9, 2021). The ZHP Defendants failed to show that information related to Valisure's pre-suit testing of branded valsartan has anything to do with this litigation.

1. *Valisure's* Data is Not Needed to Confirm Whether Diovan/Exforge Are Free of NDMA Because Reputable Health Authorities Have Done So

The ZHP Defendants argue that they need access to the NDC codes for valsartan tested by

[5] Defendants argue that neither Plaintiffs nor Valisure would be prejudiced and that "basic fairness" requires the Court to overturn the Special Master's order in favor of Defendants. In fact, Plaintiffs would be prejudiced having fully briefed numerous issues based on the discovery that existed at the time and Plaintiffs would be forced to expend considerable time and effort to assess whatever documents might be produced by the subpoena and assess whatever issues they might inject, beginning with the serious lack of reliability of the laboratory – which could never meet the Daubert criteria. The same prejudice and inefficiency would be directed to the Court as well.

Valisure prior to commencement of this litigation to determine if, according to Valisure, Diovan/Exforge also contained NDMA. [ECF 2494-1 at 1–2.] However, Health Canada publicly confirmed that branded valsartan does not contain NDMA.[6] Consistent with these results, the FDA chose not to recall either product for NDMA contamination.[7] Despite adequate information from Health Canada and the FDA confirming that there are no nitrosamines in Diovan/Exforge, the ZHP Defendants argue that the *only way* for them to determine whether these products are free of nitrosamines is to access information from Valisure, a third-party testing laboratory with a history of providing unreliable test results. [ECF 2494-1 at 1–2.] For example, on December 5, 2022, the FDA issued a letter to Valisure regarding deficiencies FDA inspectors had observed with respect to Valisure's NDMA testing—the very subject of the Valisure subpoena. [ECF 2227-8.] Specifically, the FDA inspectors observed that Valisure's NDMA testing methods were flawed, that it did not adequately address out of specification (OOS) testing results, that it used instrumentation that did not meet established specifications, and that it failed to exercise appropriate controls. [ECF 2227-8.] Defendants fail to establish any need for Valisure data on Diovan/Exforge where they could have availed themselves of test results from reliable public health authorities. [8]

[6] Health Canada, Impurities found in certain angiotensin II receptor blocker (ARB) products, also known as sartans, https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/drugs/angiotensin-receptor-blocker.html (last accessed Sept. 29, 2023).

[7] *See* FDA, *FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan)*, https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan (last accessed Sept. 29, 2023).

[8] In addition, as Special Master Vanaskie explained, "if the ZHP Defendants were of the opinion that Exforge or Diovan contain nitrosamines, they were free to conduct their own testing to confirm those beliefs. That they did not do so is no reason to open discovery that should have concluded

2. The ZHP Defendants Have Already Admitted that the Diovan/Exforge Process

Any claims of relevance by the ZHP Defendants are further undermined by their own prior admissions that tin process (referred to by ZHP as "Process I")—the only process by which Diovan/Exforge were manufactured—cannot produce NDMA. [*See*, Ex. A, ZHP02440250, at 10 ("Process I . . . will not carry this NDMA impurity.").] The ZHP Defendants argue that they need the subpoenaed information to demonstrate that Diovan/Exforge *also* contain nitrosamines, but they have already admitted that this is impossible. [*Id.*] In light of the ZHP Defendants' own chemical analysis demonstrating that NDMA cannot form in these products, there is no basis to review further testing data to determine whether it is present: the ZHP Defendants have already answered that question.

The ZHP Defendants have not established that the information sought meets the baseline requirement of discoverability: relevance. *See, e.g.*, *Raritan Baykeeper, Inc. v. NL Industries Inc.*, 2014 WL2965881 *7 (D.N.J. July 1, 2014) (finding discovery requests improper because they had "no relevance" to any element of the claim plaintiff must prove).

CONCLUSION

For the foregoing reasons, Plaintiffs request that the Court deny the ZHP Defendants' Appeal of Special Master Order 84.

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long ago." [ECF 2476 at 5.] Defendants' argument that Valisure's internal data *might* reveal that brand name valsartan contained nitrosamines and undermine Plaintiffs' theories is undermined, as Special Master Vanaskie highlighted, by the fact that Defendants never bothered to investigate this issue in the years since the 2019 Citizen's Petition was released. [*See id.*]

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